

(c) Cereal beverage, saké, or any fermented product, in conjunction with the filing of a formula.

(26 U.S.C. 5415, 5555, 7805(a))

#### FORMULAS

#### § 25.55 Formulas for fermented products.

(a) *For what fermented products must a formula be filed?* You must file a formula for approval by TTB if you intend to produce:

(1) Any fermented product that will be treated by any processing, filtration, or other method of manufacture that is not generally recognized as a traditional process in the production of a fermented beverage designated as “beer,” “ale,” “porter,” “stout,” “lager,” or “malt liquor.” For purposes of this paragraph:

(i) Removal of any volume of water from beer, filtration of beer to substantially change the color, flavor, or character, separation of beer into different components, reverse osmosis, concentration of beer, and ion exchange treatments are examples of non-traditional processes for which you must file a formula.

(ii) Pasteurization, filtration prior to bottling, filtration in lieu of pasteurization, centrifuging for clarity, lagering, carbonation, and blending are examples of traditional processes for which you do not need to file a formula.

(iii) If you have questions about whether or not use of a particular process not listed in this section requires the filing of a formula, you may request a determination from TTB in accordance with paragraph (f) of this section.

(2) Any fermented product to which flavors or other nonbeverage ingredients (other than hop extract) containing alcohol will be added.

(3) Subject to paragraph (f) of this section, any fermented product to which coloring or natural or artificial flavors will be added.

(4) Subject to paragraph (f) of this section, any fermented product to which fruit, fruit juice, fruit concentrate, herbs, spices, honey, maple syrup, or other food materials will be added.

(5) Saké, including flavored saké and sparkling saké.

(b) *Are separate formulas required for different products?* (1) You must file a separate formula for approval for each different fermented product for which a formula is required.

(2) You may file a formula for a beer base to be used in the production of one or more other fermented products. The beer base must conform to the standards set forth in § 25.15.

(c) *When must I file a formula?* (1) Except as provided in paragraph (c)(2) of this section, you may not produce a fermented product for which a formula is required until you have filed and received approval of a formula for that product.

(2) You may, for research and development purposes (including consumer taste testing), produce a fermented product without an approved formula, but you may not sell or market this product until you receive approval of the formula for it.

(d) *How long is my formula approval valid?* Your formula approved under this section remains in effect until: you supersede it with a new formula; you voluntarily surrender the formula; TTB cancels or revokes the formula; or the formula is revoked by operation of law or regulation.

(e) *Are my previously approved statements of process valid?* Your statements of process approved before January 3, 2006 are considered approved formulas under this section, provided that any finished product that could be made under the statement of process would be in compliance with the provisions of this part. You do not need to submit a formula for approval if a statement of process that remains valid covers the product.

(f) *Determinations by TTB regarding specific processes and ingredients.* (1) The appropriate TTB officer may determine whether or not use of a process not listed in paragraph (a)(1) of this section requires you to file a formula for approval. The appropriate TTB officer may also exempt the use of a particular coloring, flavoring, or food material from the formula filing requirement of paragraph (a)(3) or paragraph (a)(4) of this section upon a finding that the coloring, flavoring, or food

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material in question is generally recognized as a traditional ingredient in the production of a fermented beverage designated as “beer,” “ale,” “porter,” “stout,” “lager,” or “malt liquor.”

(2) You may request a determination from TTB on whether or not the use of a process not listed in paragraph (a)(1) of this section will require the filing of a formula or whether the use of a particular coloring, flavoring or food material may be exempted from the formula filing requirement of paragraph (a)(3) or paragraph (a)(4) of this section. You should mail your request to the Assistant Chief, Advertising, Labeling and Formulation Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Washington, DC 20220.

(i) When requesting a determination as to whether a process is subject to the formula filing and approval requirement, the request must include:

(A) A detailed description of the proposed process;

(B) Evidence establishing that the proposed process is generally recognized as a traditional process in the production of a fermented beverage designated as “beer,” “ale,” “porter,” “stout,” “lager,” or “malt liquor”; and

(C) An explanation of the effect of the proposed process on the production of a fermented product.

(ii) When requesting an exemption from the formula filing requirement in paragraph (a)(3) or paragraph (a)(4) of this section regarding coloring, flavoring, or food material ingredients, the request must include the following information:

(A) A description of the proposed ingredient;

(B) Evidence establishing that the proposed ingredient is generally recognized as a traditional ingredient in the production of a fermented beverage designated as “beer,” “ale,” “porter,” “stout,” “lager,” or “malt liquor”; and

(C) An explanation of the effect of the proposed ingredient in the production of a fermented product.

## § 25.56 Filing of formulas.

(a) *What are the general requirements for filing a formula?* (1) You must file your formula in writing. Your formula must identify each brewery where the

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formula applies by including each brewery name, address, and registry number.

(2) You must serially number each formula, commencing with “1” and continuing in numerical sequence.

(3) You must date and sign each formula.

(4) You must file two copies of each formula with TTB.

(b) *Where do I file a formula?* File your formula with the Assistant Chief, Advertising, Labeling and Formulation Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Washington, DC 20220.

(26 U.S.C. 5401, 7805)

## § 25.57 Formula information.

(a) *Ingredient information.* (1) For each formula you must list each separate ingredient and the specific quantity used, or a range of quantities used. You may include optional ingredients in a formula if they do not impact the labeling or identity of the finished product.

(2) For fermented products containing flavorings you must list for each formula: The name of the flavor; the product number or TTB drawback number and approval date of the flavor; the name and location (city and State) of the flavor manufacturer; the alcohol content of the flavor; and the point of production at which the flavor was added (that is, before, during, or after fermentation).

(3) For formulas that include the use of flavors and other nonbeverage ingredients containing alcohol, you must explicitly indicate:

(i) The volume and alcohol content of the beer base;

(ii) The maximum volumes of the flavors and other nonbeverage ingredients containing alcohol to be used;

(iii) The alcoholic strength of the flavors and other nonbeverage ingredients containing alcohol;

(iv) The overall alcohol contribution to the finished product provided by the addition of any flavors or other nonbeverage ingredients containing alcohol. You are not required to list the alcohol contribution of individual flavors and other nonbeverage ingredients containing alcohol. You may state the total alcohol contribution from these ingredients to the finished product; and